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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,480	01/29/2004	Herbert Moessler	2003_1478A	3739
513	7590	12/20/2005	EXAMINER	
WENDEROTH, LIND & PONACK, L.L.P.			KOSAR, ANDREW D	
2033 K STREET N. W.			ART UNIT	
SUITE 800			PAPER NUMBER	
WASHINGTON, DC 20006-1021			1654	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/766,480	Applicant(s) MOESSLER ET AL.	
	Examiner Andrew D. Kosar	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 9-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>20051130</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/23/05;9/8/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, the species SEQ ID NO:1, in the reply filed on September 15, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 9-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 15, 2005.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims read upon a variety of natural compositions, including a chicken, a human, a sea urchin, a pig, Atlantic cod, a mouse, a blue crab, and a fruit fly. Each comprises additional amino acids, peptides with molecular weights less than 10 kDa, minerals, vitamins, taurine, fatty acids, phospholipids, phosphatidylserines, coloring agents, e.g. porphyrins, additives and excipients, e.g. water.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7 recites the limitation "The oral dosage form" in the preamble of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 1, from which it depends does not provide sufficient support for 'The oral dosage form'. The appropriate antecedent basis appears to be to claim 6.

Claim 7 recites, "comprising 2-20 wt% peptides". It is unclear whether the composition total peptide concentration must be in a 2-20 wt%, or whether it is the peptide of claim 1 that must be 2-20 wt%, and therefore, the claims are indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by HARRIS (M.S. Harris, ed. Organ-meats-msg 7/25/2001, [Internet document], accessed 11/30/05, 38 pages, <<http://web.archive.org/web/20010725001910/http://www.florilegium.org/files/FOOD-MEATS/organ-meats-msg.text>>) in view of SULLIVAN (K.F. Sullivan, et al. J. Biol. Chem.

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1986, 261(28), pages 13317-13322), UniProt entry TBB_CHICK (accession number P09206, 3 pages) and BRADSHER (K. Bradsher. "Age-old recipe roils new Chinese Disney", 6/20/2005, 2 pages).

The instant claims are drawn to a dietary supplement mixture having neuroprotective activity, which comprises a peptide formulation, comprising a peptide having SEQ ID NO:1.

Harris teaches chicken testicles are an ingredient in a food recipe (page 28). Food recipes are art recognized as orally ingested.

Sullivan and UniProt are relied upon for the beneficial teaching that chicken testis express a protein which 'has' SEQ ID NO:1 (see UniProt, page 3, 2nd line of sequence, amino acids 256-262 and Sullivan, page 13319, protein sequence encoded by nucleotides 1500-1521).). Because the limitations of the only recited essential element are met (a peptide having SEQ ID NO:1), the composition inherently 'has a neuroprotective effect', as a compound (a peptide having SEQ ID NO:1) and its properties cannot be separated.

Bradsher is relied upon for the teaching that, "The president of Taiwan, Chen Shui-bian, announced nearly four years ago that shark's fin would not be served at his daughter's wedding. Local delicacies were served instead, like chicken testicles, which resemble slightly yellow grains of rice and are cooked in wine for a dish believed to improve virility." (page 2).

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Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by TANG (US Patent 6,7432,619 B1).

The instant claims are presented *supra*.

Tang teaches SEQ ID NOs:251 and 252, which are proteins that ‘have’ instantly claimed SEQ ID NO:1. Tang teaches, “The polypeptides of the invention can also be [...] used as a food supplement.” (column 3, line 67- column 4, line 2). Tang teaches that, “polypeptide compositions of the invention may further comprise an acceptable carrier” (column 3, lines 28-24 and column 23, lines 24-26). Because the limitations of the only recited essential element are met (a peptide having SEQ ID NO:1), the composition inherently ‘has a neuroprotective effect’, as a compound (a peptide having SEQ ID NO:1) and its properties cannot be separated.

Tang teaches that the proteins may be expressed in a myriad of host cells, including prokaryotic hosts, e.g. *E. coli* (column 16, lines 26-29), and provides a comprehensive list of hosts (column 20, **3.5 Hosts**) stating that, “Any host/vector system can be used to express one or more of the ORGs of the present invention.” (column 20, lines 50-51), including “Various mammalian cell culture systems” (column 21, line 1) and “Alternatively, it may be possible to produce the proteins in lower eukaryotes such as yeast or insects or in prokaryotes such as bacteria (column 21, lines 32-34) or “as the product of transgenic animals, e.g. as a component of the milk of transgenic cows, goats, pigs, or sheep” (column 24, lines 48-52).

Cells expressing the protein necessarily have additional components, as recited in the instant claims (as described *supra* under 35 USC § 101). Further, the milk of a cow is an oral dosage form.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over TANG, as applied to claims 1-6, *supra*, in further view of KAMAREI (US Patent 5,985,339) and/or GOHMAN (US Patent 6,511,696 B2).

The instant claims are presented *supra*. The teachings of Tang are presented *supra*.

Kamarei teaches a variety of nutritional compositions (e.g. examples 1-28) which meet the requirements of a Nutritional Supplement for human use (claim 11) and compositions where the peptides are between 2-20 wt% (e.g. Table 12, 10g protein/composition), and describes the additional elements, e.g. vitamins, minerals, excipients, colorings, etc. that are present (Tables 1-12), including vitamin C, calcium, copper, copper sulfate, soy lecithin, isolated soy proteins, natural and artificial flavor, corn oil, canola oil, calcium caseinate, lactose-free skim milk, and corn syrup solids. Other compositions have milk protein concentrate and oat fiber (e.g. Table 11). Kamarei teaches that, "When the composition is used as a nutritional supplement [...], the protein source can also include enzymatically hydrolyzed protein (peptides), amino acids and combinations thereof." (column 12, lines 38-41).

Gohman teaches infant formula with free amino acids (title, throughout). Gohman teaches the essential and non-essential amino acid profiles of two infant formulae (Tables 3 and 4, respectively) and the additional components of a formula (column 10, lines 1-31).

The difference between that which is instantly claimed and that which is taught in Kamarei, is that while Kamarei teaches dietary supplement compositions, Kamarei does not teach the compositions having SEQ ID NO:1 or the weight percent of the additional amino acids.

As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art."

In the instant case, both Kamarei and Tang teach compositions which are food supplements/nutritional compositions, and thus in view of *Kerkhoven*, it is *prima facie* obvious to have combined the two compositions of Kamarei and Tang to form a third composition which is a food supplement/nutritional composition.

With regards to the recited peptide and amino acid concentration, it would have been obvious to one skilled in the art at the time of invention to determine all optimum and operable conditions (e.g. concentrations of peptides and/or amino acids), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation. ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP § 2145.05).

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

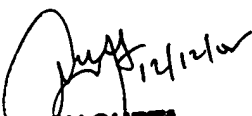
NO CLAIMS ARE ALLOWED.


The prior art made of record on the attached PTO-892 and not relied upon in any rejection is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


ANISH GUPTA
PRIMARY EXAMINER


Andrew D. Kosar, Ph.D.
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